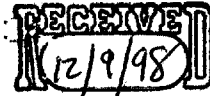




Information - data resources
Conferences - symposia - publications
Growing Projects

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Alternative Medicine Foundation, Inc.
President: Jackie Wootton, MEd



Elizabeth A. Yetley, Ph.D.
Director
Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street, S.W.
Washington, D.C. 20204

December 8, 1998

Re: FFDCA § 403(r)(6) Notification

Dear Dr. Yetley:

In accordance with section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 343(r)(6), and implementing Food and Drug Administration regulation, 21 C.F.R. § 101.93 (62 Fed. Reg. 49883, 49886 (Sept. 23, 1997)), we submit on behalf of the manufacturer/notifying firm this notification that a statement is included in labeling its dietary supplement:

Manufacturer: PADMA AG
Dammstrasse 29
CH-8702 Zollikon
Switzerland

Text of statement: The particular combination of herbs in PADMA BASIC is used . . . to support our body's natural mechanisms and to help maintain good health.

The undersigned certifies that the information contained in this notice is complete and accurate, and that the notifying firm has substantiation that the statement is truthful and not misleading.

Respectfully submitted,

Jackie Wootton, M.Ed.
President

5411 W. Cedar Lane, #205A
Bethesda, MD 20814
Telephone (301) 581-0116 Fax (301) 581-0119

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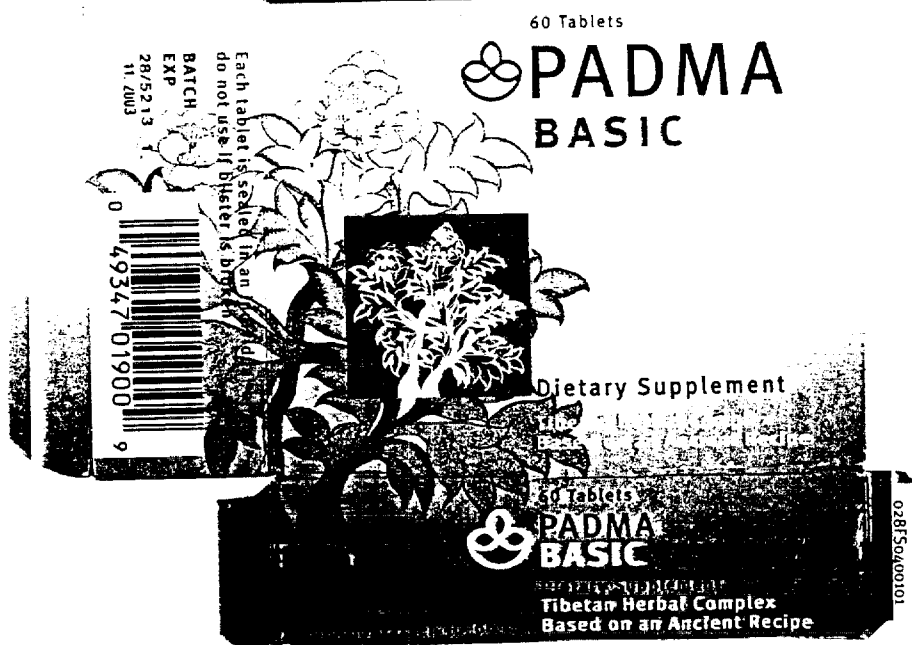
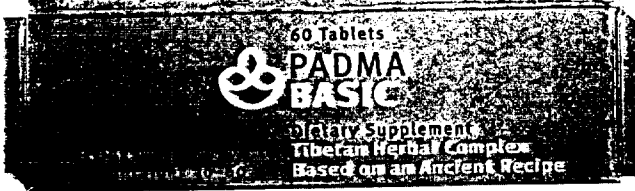
Supplement Facts		
Serving Size 1-2 Tablets		
	Amount Per Tablet	% Daily Value
Calcium (as Calcium sulfate)	5.9 mg	< 1%
Proprietary blend of herbs and spices	382 mg	*
Iceland Moss, Saussuria, Margosa, Cardamom, Myrobalan, Red Sandalwood, Allspice, Bengal Quince, Columbine, Licorice, Ribwort, Knotgrass, Golden Cinquefoil, Cloves, Gingerlily, Heartleaved Sida, Valerian, Wild Lettuce, Marigold, Camphor		
* Daily Value not established		

Other Ingredients: Sorbitol, Silicon dioxide.

Suggested use 1-2 tablets 2-3 times a day

Statements on this label have not been approved by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

Manufactured by
Padma
Silver Brands, Inc.,
Silver Lake, WI 53170





PADMA BASIC Dietary Supplement

Tibetan Herbal Complex Based
on an Ancient Recipe

PADMA BASIC is an herbal formulation based on a traditional Tibetan recipe. It consists of a carefully balanced preparation of 19 dried and milled herbs and spices, together with natural camphor and calcium sulfate. Only unadulterated natural substances of high quality are used for production.

The ingredients are selected, according to ancient Tibetan philosophy and practice, by their taste and smell. The active ingredients include tannins, bioflavonoids and essential oils.

Ingredients



Each tablet contains:
Iceland Moss, Saus-
suria, Margosa, Car-
damom, Myrobalan,
Red Sandalwood,
Allspice, Bengal

Quince, Calcium Sulfate, Columbine,
Licorice, Ribwort, Knotgrass, Golden
Cinquefoil, Cloves, Gingerlily, Heart-
leaved Sida, Valerian, Wild Lettuce,
Marigold, Camphor.

Suggested use



For the first week,
take 1-2 tablets,
3 times daily, pre-
ferably on an empty
stomach, at least 30
minutes before or
approximately 2 hours after a meal.
After the first week, take 1-2 tablets
on waking and 1-2 before bedtime.

It is recommended that the tablets
be chewed before swallowing with
an adequate amount of water –
(1-2 glasses). During the first few
days, the taste may appear strange,
even unpleasant. This is due to the
unfamiliar aromatic ingredients,
and will soon pass.

History of the product



In the Tibetan tradi-
tion, health and
wellness are des-
cribed in terms of
maintaining the
equilibrium of the

body. The Tibetans speak of the
«harmony of nature's organism».
This includes not just the relation-
ship between the different organs of
the body but also the complex inter-
relationships between humans, the
animal world, and the plant kingdom.
Circumstances, such as diet, life
style, mental and seasonal condi-
tions can disturb this balance. The
particular combination of herbs in
PADMA BASIC is used, according to
this ancient practice, to support our
body's natural mechanisms and to
help maintain good health.

According to the Tibetan doctrines,
it is not one specific ingredient but,
rather, the appropriate combination
of many ingredients that yields the
desired balancing effect. Tibetan
formulas are described as stimula-
ting the body with gentle impulses
that are aimed at supporting the
body's natural state of health.
These impulses, which are said to
prompt the system to activate its
own health giving powers, can be
likened to messengers or carriers of
information.

The swiss company and the method
of production



PADMA BASIC is
produced in a spe-
cialized plant by the
Swiss company,
PADMA Inc. The
dried and ground

natural ingredients are carefully
combined and compressed into tab-
lets. Some of the herbs are grown in
Switzerland in conformity with orga-
nic farming principles, others are
harvested in other regions of
Europe, and in India. Thorough qua-
lity control ensures that only top
quality, uncontaminated plants and
plant substances are used.

PADMA Inc. is a well established
company and a respected house-
hold name in Switzerland where
PADMA products have been used
for over 20 years. PADMA's good
reputation has spread through
Europe and into Canada, where its
products are also widely available.

No other products from PADMA Inc.
are currently available in the USA.

Warning



Always consult a
qualified health care
provider if you have
or suspect you may
have a health prob-
lem. Pregnant and
lactating women should consult a
physician before using any product.

Statements on this package insert have not
been approved by the Food and Drug
Administration. This product is not intended to
diagnose, treat, cure or prevent any disease.

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